INPLASY PROTOCOL

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Conflicts of interest:
The authors declare no conflicts of interest.

Effectiveness and safety of electroacupuncture for insomnia: a protocol for an overview of systematic reviews and meta-analysis

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Review question / Objective: This overview is an effort to summarize the available evidence from current systematic reviews for the efficacy of electroacupuncture therapy for insomnia.

Condition being studied: Insomnia is a common disease characterized by difficulty falling and/or staying asleep, and accompanied by irritability or fatigue during wakefulness. It is widely reported that insomnia is one of the most extensive mental disorders which the incidence rate is estimated to be about 10%. Insomnia can have serious influences on patients' health and quality of life. Electroacupuncture is reported to be efficacious and widely used for the treatment of insomnia in China. This overview aims to summarize the available evidence from current systematic reviews for the efficacy of electroacupuncture therapy for insomnia.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 21 August 2020 and was last updated on 21 August 2020 (registration number INPLASY202080087).

INTRODUCTION

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health and quality of life. Electroacupuncture is reported to be efficacious and widely used for the treatment of insomnia in China.This overview aims to summarize the available evidence from current systematic reviews for the efficacy of electroacupuncture therapy for insomnia.

METHODS

Participant or population: Patients with insomnia.

Intervention: The therapeutic intervention applied in the experimental group was Electroacupuncture（EA）. EA combined with other therapies were included as well if the combined therapy had the both same groups. However, other acupuncture methods (nonelectroacupuncture) and dry needling not based on oriental medicine and meridian theory were excluded. No specific criteria were set regarding the needle size, acupoint selection, current stimulation frequency, intensity, retention time, and treatment course.

Comparator: The controlled group were blank control, placebo, psychological control, drug therapy or physical therapy modalities done by the general physician. Studies in which the control group received usual care were also eligible for inclusion.

Study designs to be included: All systematic reviews and meta-analysis on the use of electroacupuncture for insomnia.

Eligibility criteria: Published systematic reviews which were reported in Chinese or English, and meet the "PICOS", will be considered for inclusion in this overview.

Information sources: Pubmed, Embase, Cochrane Library, Chinese Biomedical Literatures Database(CBM), China National Knowledge Infrastructure (CNKI) , WangFang Database (WF), Chinese Scientific Journal Database (VIP).

Main outcome(s): The sleep quality values according to the Pittsburgh Sleep Quality Index (PSQI).

Additional outcome(s): 1.Insomnia severity according to the Insomnia Severity Index (ISI). 2.Quality of life measured by validated assessment tools such as the 36-Items Short Form Health Survey (SF-36). 3.Syndrome according to standards for assessing TCM. 4.Adverse events caused by WNA, such as dizziness, nausea, vomiting, weariness, etc.

Data management: (1)We will use NoteExpress and Excel software to extract data. The content will be saved in electronic form. (2)Different review authors will independently screen the titles and abstracts of records obtained by searching the electronic databases to determine potential eligibility. Full texts screening and data extraction will be conducted afterwards independently. Any disagreement regarding study selection will be resolved through discussion or arbitrated by the third author if necessary. In this step, we will use NoteExpress . (3)The research team designed structured data extraction tables, including: the first author, nationality, publication year, patients' basic information, sample size, intervention measures of test group, intervention measures of controlled group, qualitative evaluation method, target outcome (including primary outcome measures and secondary outcome measures), etc. Different review authors will independently extract data. Any disagreement regarding data extraction will be resolved through discussion or arbitrated by the third author if necessary. In this step, we will use Excel.

Quality assessment / Risk of bias analysis: Assessment of Multiple Systematic Reviews 2 (AMSTAR-2) measurement tool,Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA), Grading of Recommendations Assessment, Development and Evaluation(GRADE) approach.

Strategy of data synthesis: We will provide a narrative description of the findings of the included systematic reviews (SRs). Tables will be produced to detail the included studies and their outcomes. In addition, we will synthesis these reviews and provide pooled treatment effects for all SRs which include the main outcome: the sleep quality values according to the Pittsburgh Sleep Quality Index (PSQI). If necessary,this study will use RevMan5.4 software for data integration and analysis. The measurement data will use the mean difference (MD) as the effect indicator, and the count data will use the odds ratio (OR) as the effect index. Each effect indicator will be given as a point estimate with 95% confidence interval.The heterogeneity and size of each study result will be judged using statistical methods. For studies with no statistical heterogeneity, the analysis will be performed using a fixed-effect model, whereas a randomized effects model will be applied if for studies with significant statistical heterogeneity.

Subgroup analysis: If heterogeneity is evaluated as significant (I2≥50%) and the trials included are adequate, we will perform a subgroup analysis to explore the potential source of the heterogeneity according to the difference in participant characteristics, interventions, controls, and outcome measures.

Sensibility analysis: According to sample size, methodological quality, and the effect of missing data, sensitivity analysis will be carried out to identify the quality and robustness of the meta-analysis result when the outcome analyses involve a large degree of heterogeneity.

Language: No restriction.

Country(ies) involved: China.

Other relevant information: None.

Keywords: electroacupuncture, insomnia, protocol, overview.

Contributions of each author:
Author 1 - Xingchen Zhou - conceive and design this protocol.
Author 2 - Jun Xiong - Revise this protocol; search strategy.
Author 3 - Zhenhai Chi - Data collection; analysis of results.